

effective treatment for hay fever, low vitality, arthritis, neuritis, anemia, low blood pressure, and diabetes, and that the *Cab-Ext* was an adequate and effective treatment for ulcers and inflammation of the stomach.

**DISPOSITION:** 2-18-55. No claimant having appeared, the court entered decrees of condemnation and ordered that the articles be destroyed. Thereafter, a motion was made by Dr. A. V. Downs to set aside such decrees, and on 9-20-55, the court handed down the following decision on the motion:

**SOLOMON, District Judge:** "The motion to set aside the decree in condemnation in each of the above cases is denied.

#### COMMENT

"The respondent seeks to set aside and vacate the Decree of Condemnation entered in both of the cases on the 18th day of February, 1955. In Civil 7819, the court ordered 984 bottles of tablets labeled 'Alfa-Tone,' together with 500 product labels and 100 descriptive leaflets destroyed. In Civil 7820, the court ordered 480 bottles of tablets labeled in part 'Cab-Ext,' together with 200 descriptive leaflets destroyed.

"There is no contention that the procedural requirements governing these cases have not been strictly met. The respondent was given ample time within which to answer the libel or otherwise appear, and he failed to do so.

"However, respondent contends that the tablets themselves are not harmful or deleterious and that if the leaflets which accompanied the tablets are destroyed, the legitimate purposes of the Federal Food, Drug, and Cosmetic Act will have been accomplished.

"I have examined the report of the analyses of the tablets made by the Charlton Laboratories for the respondent and by the Division of Nutrition of the Department of Health, Welfare, and Education for the libelant. Neither report shows that the tablets are themselves either harmful or deleterious. However, I am convinced that these tablets will serve no worthwhile purpose in the treatment of disease or in the remedying of nutritional deficiencies.

"The accompanying literature indicates that wild and unsupported claims were made concerning the effectiveness of these tablets in the treatment of disease. Even though the literature is destroyed, the return of these tablets to the defendant would, in all probability, result in similar claims being made orally. In my opinion, these tablets are salable only if accompanied by false and misleading statements, and their return to the defendant will only lead to exploitation of the people to whom they are sold."

**4759. Hyrocain.** (F. D. C. No. 37097. S. No. 64-762 L.)

**QUANTITY:** 49 display cartons, 12 cartoned tubes each, at Seattle, Wash.

**SHIPPED:** 6-8-54, from New York, N. Y., by the American Pharmaceutical Co.

**LABEL IN PART:** (Tube) "APC One Ounce Hyrocain Antibiotic, Antihistaminic And Anesthetic Cream Containing per Gram: Pyrillamine Maleate 10 mg., Benzocaine 10 mg., Tyrothricin 0.5 mg., in a special soothing, non-irritant, non-staining washable base."

**ACCOMPANYING LABELING:** Leaflet designated "Completely New! Antibiotic, Anesthetic, Antihistaminic Cream Helps Heal," a 2-page letter designated "Hyrocain A New Antibiotic and Anaesthetic Cream," and window banners designated "Hyrocain Stops Itch."

**LIBELED:** 9-21-54, W. Dist. Wash.

**CHARGE:** 502 (a)—the labeling of the article when shipped contained false and misleading representations that the article was an adequate and effective treatment for acne, pimples, eczema, skin infections, folliculitis, seborheic dermatitis, nummular eczema, neurodermatitis, and herpes genitalis; and the above-mentioned 2-page letter contained the statement "In order for this product to be released to the public it had to go through clinical testing in a leading allergy clinic and evidence presented to the Food and Drug Administration to

prove the efficacy, etc., of HYROCAIN," which statement represented and suggested that the Food and Drug Administration considers the article effective in the conditions and for the purposes for which it was offered, and which was false and misleading since the Food and Drug Administration does not consider the article effective in all of the conditions and for all of the purposes for which the article was offered.

DISPOSITION: 11-24-54. Consent—claimed by American Pharmaceutical Co. and relabeled.

4760. *Cacodyne*. (F. D. C. No. 33297. S. No. 33-012 L.)

QUANTITY: 20,300 ampuls, 10 cc. each, of *Cacodyne* (Colloidal Isotonic Iodine Solution) and 20,300 ampuls, 1 cc. each, of *Cacodyne* (Sodium Cacodylate) at Chicago, Ill., in possession of Research Medications, Inc.

SHIPPED: Between 9-1-50 and 12-19-51, from Tuckahoe and New York, N. Y.

LABEL IN PART: "10 cc. Size *Cacodyne* Each 10 cc. contains 0.2 percent Colloidal Isotonic Iodine Solution" or "*Cacodyne* Each cc. contains 7 gr. of Sodium Cacodylate (Arsenic derivative)."

ACCOMPANYING LABELING: Brochures entitled "*Cacodyne* An Isotonic Colloidal \* \* \* for all arterial diseases" and reprints entitled "A Regimen for Restoration of Cardiovascular Reserve," "A New Management for the Sustained Relief of Angina Pectoris and Coronary Disease," "Decisiveness Imperative in Cardiovascular Management," and "Cardiovascular Disease, Its Treatment Based on Control of Hypertension and Restoration of Coronary Efficiency."

RESULTS OF INVESTIGATION: The articles, after their receipt at Chicago, Ill., were in part repackaged by the consignee, Research Medications, Inc., into combination packages containing 1 ampul of each article; and, when shipments of the repackaged articles were made by the consignee, there would be enclosed in the shipping container a copy of the above-mentioned brochure containing the statement "Reprints and other information on request."

LIBELED: 6-20-52, N. Dist. Ill.

CHARGE: 502 (a)—the labeling accompanying the articles while held for sale contained false and misleading representations that the articles were an adequate and effective treatment for all arterial diseases and all forms of circulatory impairment.

DISPOSITION: Research Medications, Inc., claimant, consented to the entry of a decree, and on 6-26-52, an order was entered condemning the articles and providing for their release to the claimant for the purpose of bringing them into compliance with the law. Thereafter, a dispute arose between the claimant and the Government as to the disposition of certain of the literature accompanying the articles, and the claimant filed a petition requesting the court to vacate the consent decree and to set the matter down for a hearing on its merits.

On 12-18-52, the court entered an order which permitted the claimant to file an answer, but left the consent decree standing as security; the court further ordered that that portion of the article which bore labeling which had been approved by the Food and Drug Administration during its negotiations with the claimant be released to the claimant, but that the accompanying labeling be held intact. Thereafter, the claimant filed a motion for particulars, or for more definite allegations, which motion was granted by the court on 12-24-52. The information requested by such motion was furnished by the Government